

K 061960

SEP - 5 2006

## **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Submitter:** CAS Medical Systems, Inc.

**Address:** 44 East Industrial Rd. Branford CT. 06405 USA

**Contact:** Ron Jeffrey - Director, Regulatory Affairs  
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**Prepared:** July 10, 2006

**Trade Name:** FORE-SIGHT™ Cerebral Oximeter Monitor

**Common Name:** Model 2040

**Classification Name:** Cerebral Oximeter (870.2700)

## **EQUIVALENCE (Predicate Device)**

The FORE-SIGHT™ Cerebral Oximeter Monitor, Model 2040 is equivalent to the following devices:

- ❖ CAS Adult Cerebral Oximeter Model 2040 (K051257)
- ❖ Somanetics INVOS® 5100 / 5100A Cerebral Oximeter (K001842 / K960614);
- ❖ Spectros T-Stat™ 303 Microvascular Tissue Oximeter (K040684);

## **DESCRIPTION**

The Cerebral Oximeter Monitor measures cerebral tissue oxygen saturation allowing the clinician to accurately determine absolute levels of brain tissue blood oxygen saturation and brain venous oxygen saturation in the brain. This measurement can be of significant value in numerous acute care (OR, ICU, ER) situations, providing health care professionals with information to guard against neurological injuries due to compromised brain oxygenation, which can occur during many surgical and clinical procedures.

The Cerebral Oximeter Monitor consists of an optical transducer containing a laser light source and photodiode detectors, and a graphic display monitor with user interface. The non-invasive, reflection mode, optical transducer is placed on the forehead of the subject via a disposable sensor attachment to determine cerebral oxygenation. The Cerebral Oximeter Monitor is safe to use, because it is designed to operate as a Class I laser product, the safest FDA laser classification. Additional safety features include a laser interlock system designed to prevent laser operation in case the optical transducer is not securely attached to the subject. A patent-protected algorithm optimizes accuracy of the device for measurements of absolute cerebral tissue oxygen saturation and, in conjunction with pulse oximetry, provides absolute readings of brain venous oxygen saturation.

### **Cerebral Oximeter Monitor Intended Use**

The non-invasive FORE-SIGHT Cerebral Oximeter Monitor, model 2040 should be used as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain. When used with FORE-SIGHT Large sensors, the Cerebral Oximeter Monitor is indicated for use with adults and children over 40 Kg. When used with FORE-SIGHT Small sensors, the Cerebral Oximeter Monitor is indicated for infants. The Cerebral Oximeter Monitor should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the Cerebral Oximeter Monitor has not been demonstrated in disease states.

### **Cerebral Oximeter Monitor Technology Compared to Predicate Devices**

The FORE-SIGHT Cerebral Oximeter Monitor compares substantially to one or more of the cited predicate devices in that they use fundamentally the same optical operating principle, called diffuse reflectance spectroscopy. All cited monitors use light to probe a cross-section tissue microvasculature (mixed bed of arterioles, capillaries and venules). The Cerebral Oximeter Monitor and predicate devices analyze light returning from tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region. All cited monitors calculate oxygen saturation. This value reflects the percentage of oxygenated hemoglobin in the sampled tissue.

### **Non-Clinical Performance Testing to Demonstrate Substantial Equivalence**

The Cerebral Oximeter Monitor has been tested to the following standards in accordance with CAS Medical Systems Product Performance Specifications. The following non-clinical tests have been performed:

- UL60601-1 (w/ CSA 22.2 No. 60601-1) Safety testing for use of the UL Classified mark;
- IEC60601-1 Safety of Medical Electrical Equipment;
- IEC60601-1-2: 2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- IEC60601-1-1 Safety of Medical Electrical Systems;
- IEC60825-1: Safety of Laser Products (with amendments A1 and A2);
- Testing specified in the Reviewer Guidance for Premarket Notification Submissions - (CAS 21-07-0076) - Applicable portions;
- VP/VR 050011 - Monitor Software Validation Plan / Report;
- VP/VR 050012 - System Validation Plan / Report;
- VP/VR 050014 - Hardware Verification Plan / Report;
- VP/VR 050051 - Storage and Transport Environment Test Report.

### **Clinical Testing to Show Substantial Equivalence**

**Adult Subject Validation:** Clinical data on adult subjects was collected at the Duke University Medical Center in Durham, North Carolina. In this study, healthy adult volunteers were subjects for comparison using an internal jugular bulb catheter on the subject's right side and a radial arterial line on the left. Two sensors from the Cerebral Oximeter Monitor were placed bilaterally on the patient's forehead. Hypoxic mixtures of gas were delivered and data was collected in 5 minute intervals during periods of ascending and descending concentrations. At each data collection point, blood samples were drawn simultaneously from the jugular bulb and the radial arterial catheters and analyzed for hemoglobin oxygen saturation using a co-oximeter. The patient was monitored and the protocol stopped if SpO<sub>2</sub> values from a pulse oximeter reached 70%.

**Infant Subject Validation:** Clinical data was collected at the Children's National Medical Center in Washington, DC, and the Children's Hospital of Atlanta (CHOA), Emory University, Atlanta, GA, from subjects undergoing veno-venous Extracorporeal Membrane Oxygenation (VV-ECMO) with cephalad catheterization. In this study, cerebral venous oxygen saturation (SjvO<sub>2</sub>) measured from blood samples obtained from the internal jugular vein via the cephalad catheter, along with pulse oximetry arterial oxygen saturation (SaO<sub>2</sub>) data, were recorded from VV-ECMO neonates without alteration to patient care or blood oxygenation levels while being monitored by the Cerebral Oximeter Monitor over a period of several days for each subject.

### Conclusions Drawn from Clinical and Non-Clinical Testing

The data is presented as Root Mean Squared Error ( $RSME = \sqrt{\text{bias}^2 + \text{precision}^2}$ ) for each measured parameter to determine the accuracy of the monitor. RSME accounts for errors relating to both the bias and precision (1 standard deviation) in calculating accuracy. Note that RSME values are approximately equal to the precision or one standard deviation when the bias is small.

**Adult SctO2:** Using the FORE-SIGHT Large sensor, the Cerebral Oximeter SctO2 showed a strong correlation with the reference SctO2 over the spectrum of values between 45 to 95%. The RSME for the Cerebral Oximeter Monitor SctO2 compared to reference SctO2 derived from co-oximetry of arterial (SaO2) and jugular bulb (SjvO2) blood samples was  $\pm 4\%$ , based on Equation 1 below.

**Infant SctO2:** Using the FORE-SIGHT Small sensor, the Cerebral Oximeter SctO2 showed strong agreement with the reference SctO2 over the spectrum of values between 50 to 95%. The RSME (1 standard deviation) for the Cerebral Oximeter Monitor SctO2 compared to the reference SctO2 derived from pulse oximetry measured arterial oxygen saturation SaO2 and co-oximetry measured internal jugular vein venous oxygen saturation (SjvO2) from blood samples was  $\pm 5\%$ , based on Equation 1.

$$\text{Reference SctO2\%} = \text{SaO2} \times 0.3 + \text{SjvO2} \times 0.7$$

*Equation 1*

The Cerebral Oximeter Monitor SctO2 value represents oxygen saturation in the brain tissue microvasculature containing venous and arterial blood volume at a ratio of 70:30.

**Adult SvO2:** Using the FORE-SIGHT Large sensor, the Cerebral Oximeter SvO2 showed a strong correlation with the reference SjvO2 over the spectrum of values between 35 to 90%. The RSME for the Cerebral Oximeter Monitor SvO2 compared to reference SjvO2, derived from co-oximetry of the jugular bulb blood samples was  $\pm 5.5\%$ . SvO2 was determined from Equation 2 below.

**Infant SvO2:** Using the FORE-SIGHT Small sensor, the Cerebral Oximeter SvO2 showed strong agreement with the reference cephalad internal jugular vein SjvO2 over the spectrum of values between 40 to 90%. The RSME for the Cerebral Oximeter Monitor SvO2 compared to reference SjvO2, measured from co-oximetry of the internal jugular vein blood samples, was  $\pm 7\%$ . SvO2 was determined from Equation 2.

$$\text{SvO2} = (\text{SctO2} - \text{SaO2} \times 0.3) / 0.7$$

*Equation 2*

In the above expression, SaO2 is arterial oxygen saturation from a pulse oximeter and SctO2 is determined by the Cerebral Oximeter Monitor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 5 2006

CAS Medical Systems, Inc.  
% Mr. Ron Jeffrey  
Director, Regulatory Affairs  
44 East Industrial Road  
Branford, Connecticut 06405

Re: K061960

Trade/Device Name: FORE-SIGHT™ Cerebral Oximeter Monitor, Model 2040  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: DQA, MUD  
Dated: July 10, 2006  
Received: July 11, 2006

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

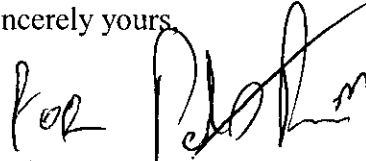
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Ron Jeffrey

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', written over a horizontal line.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K061960

Device Name: FORE-SIGHT™ Cerebral Oximeter Monitor, Model 2040

Indications for Use: The non-invasive FORE-SIGHT Cerebral Oximeter Monitor, model 2040 should be used as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain. When used with FORE-SIGHT Large sensors, the Cerebral Oximeter Monitor is indicated for use with adults and children over 40 Kg. When used with FORE-SIGHT Small sensors, the Cerebral Oximeter Monitor is indicated for infants. The Cerebral Oximeter Monitor should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the Cerebral Oximeter Monitor has not been demonstrated in disease states.


Prescription Use ☒ \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

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Division of General, Restorative  
and Neurological Devices

510(k) Number K061960